

## Annotated Case Report Form (aCRF)

### Demographics Page

Patient ID: \_\_\_\_\_

Visit Date: \_\_\_\_\_

Age: \_\_\_\_\_ Sex: \_\_\_\_\_ Race: \_\_\_\_\_

Annotation: (DM Domain – STUDYID, USUBJID, AGE, SEX, RACE, RFSTDTC)

### Adverse Events Page

Event Term: \_\_\_\_\_

Start Date: \_\_\_\_\_ End Date: \_\_\_\_\_

Severity: \_\_\_\_\_ Serious? \_\_\_\_\_ Outcome: \_\_\_\_\_

Annotation: (AE Domain – AETERM, AESTDTC, AEENDTC, AESEV, AESER, AEOUT)

### Laboratory Results Page

Lab Test: \_\_\_\_\_

Collection Date: \_\_\_\_\_

Result Value: \_\_\_\_\_ Units: \_\_\_\_\_ Normal Range: \_\_\_\_\_

Annotation: (LB Domain – LBTEST, LBDTC, LBORRES, LBORRESU, LBNRIND)

### Concomitant Medications Page

Medication Name: \_\_\_\_\_

Start Date: \_\_\_\_\_ End Date: \_\_\_\_\_

Dose: \_\_\_\_\_ Frequency: \_\_\_\_\_ Route: \_\_\_\_\_

Annotation: (CM Domain – CMTRT, CMSTDTC, CMENDTC, CMDOSU, CMDOSFRQ, CMROUTE)